510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K102096

OCT 4 2010

1. **Submitter's Identification:**

Mr. Xiaolin Shen
Syntex Healthcare Products Co., Ltd
No. 1 Fanjiazhuang Industrial, Zone,
Xinji City, Hebei Province, China 052360
Tel: 86-311-83980319

Date Summary Prepared: June 7, 2010

2. **Name of the Device:**

Syntex Healthcare Products Co., Ltd
Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue)

3. **Predicate Device Information:**

Medline Industries Incorporated
Mediguard Powder Free Nitrile Examination Glove (Blue)- Tested for use with Chemotherapy (K093726)

4. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Polymer Patient Examination Gloves, 80 LZA, and meets all requirements of ASTM standard D 6319-00a (2005)e1.

5. **Intended Use:**

A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Chemotherapy Drug	Average BDT
Fluorouracil	>240 min.
Etoposide (Toposar)	>240 min.
Cyclophosphamide (Cytoxan)	>240 min.
Carmustine	2.03 min.
Thiotepa	25.23 min.

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Paclitaxel (Taxol)	>240 min.
Doxorubicin Hydrochloride	>240 min.
Dacarbazine (DTIC)	>240 min.
Cisplatin	>240 min.

Please note that Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes.

6. **Comparison to Predicate Devices:**
Syntex Healthcare Products Co., Ltd's Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs is substantially equivalent in safety and effectiveness to the Medline Industries, Incorporated's Mediguard Powder Free Nitrile Examination Glove (Blue)- Tested for use with Chemotherapy.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:**

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a (2005)e1	Meets
Physical Properties	ASTM D 6319-00a (2005)e1	Meets
Freedom from holes		Meets
Residual Powder Test	ASTM D 6319-00a (2005)e1 ASTM D6124-06	Meets
Primary Skin Irritation and Skin Sensitization	ISO 10993 Part 10 16CFR 1500.41 16CFR 1500.3	Meets
Resistance to Permeation	ASTM D6978-05	See Data in Section 5

8. **Labeling:**
Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs with a chemotherapy claim, tested per ASTM D6978-05, and provide protection against: Fluorouracil, Etoposide (Toposar), Cyclophosphamide (Cytoxan), Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin. Do not use with Carmustine and Thiotepa. The tested chemotherapy drugs' breakthrough detection times, refer to item 5 in this summary for details.
We do not claim our gloves as hypoallergenic on our labels.

9. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

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10. **Conclusions:**

Syntex Healthcare Products Co., Ltd's Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs conform fully to ASTM D 6319-00a (2005)e1 standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Drawn from the complete list of non-clinical tests, the device is as safe and effective as the legally marketed predicate device K093726 Mediguard Powder Free Nitrile Examination Glove (Blue) Tested for Use with Chemotherapy Drugs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Syntex Healthcare Products Company, Limited
C/O Ms. Kathy Liu
Surprotect Incorporated
3973 Schaefer Avenue
Chino, California 91710

OCT 4 2010

Re: K102096
Trade/Device Name: Powder Free Nitrile Examination Glove, Tested for Use With Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: September 7, 2010
Received: September 8, 2010

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment A

INDICATION FOR USE

510 (k) NUMBER (IF KNOW): K102096
APPLICANT: Syntex Healthcare Products Co., Ltd
DEVICE NAME: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)

INDICATIONS FOR USE:

A patient examination glove is disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

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Please note that Carmustine and Thiotepa have extremely low permeation times of less than 30 minutes.

Prescription Use _____ AND/ OR Over-The-Counter-Use ✓
(Part 21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Elizabeth B. Claverie-Wilson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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